



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,503	02/09/2001	Sanjay Sethi	11520.0228	7097

7590                    08/21/2003

Ranjana Kadle  
Hodgson Russ LLP  
Suite 2000  
One M&T Plaza  
Buffalo, NY 14203-2391

[REDACTED]  
EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
1654	[REDACTED]

DATE MAILED: 08/21/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/780,503	SETHI ET AL.
	Examiner	Art Unit
	Louise N. Leary	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 11-20 is/are allowed.  
 6) Claim(s) 1,4 and 8-10 is/are rejected.  
 7) Claim(s) 2,3 and 5-7 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 09 February 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: _____                                    |

1. Claims 1-20 are pending in this application.
2. The rejection of claims 1-2, 4-11 and 13-20 under 35 USC 103(a) as unpatentable over Tsang et al (Chest/V.117/2, February 2000) has been withdrawn in view of applicant's request for reconsideration and the Declaration submitted under 37 C.F.R. 1.13.

3. NEW GROUNDS OF REJECTION:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 8-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsumoto (Verhandelingen-Koninklijke Academie voor Geneeskunde van Belgie [Verh K Acad Geneeskd Belg] 1995; V 57(2), pp. 109-22, (Abstract Only).

Matsumoto discloses a method for analyzing sputum to diagnose pathogenesis of chronic *Pseudomonas aeruginosa* lower respiratory tract infections. Matsumoto discloses that diffuse panbronchiolitis is a representative disease of chronic *Pseudomonas aeruginosa* infections. Matsumoto also reports documenting a significant correlation between neutrophil numbers and neutrophil elastase levels in

sputum from patients with chronic airway diseases. Thus, Matsumoto disclose the invention claimed except for specifically describing a reference standard.

However, regarding the reference standard described in the instant claims, Matsumoto discloses the use of clinical research methods that obtains measurement data showing a correlation between neutrophil numbers and elastase levels in samples from patients with chronic airway diseases. The Matsumoto disclosure therefore discloses or suggests the use of a reference standard in the methods described which anticipates or renders obvious all the limitations of the invention claimed.

The burden of proof is on applicants to show patentably distinct differences between the Matsumoto methods disclosed and the methods claimed in the instant invention.

4. The Mikami, M reference (Nihon Kyobu Shikkan Gakkai zasshi , 1991 Jan; V.29(1), pp.72-83, states ["The concentration and activity of neutrophil elastase (NE) in sputa were measured in 24 patients with chronic respiratory diseases such as diffuse pan-bronchiolitis, bronchiectasis and chronic bronchitis."] and has been cited to further show the state of this art.

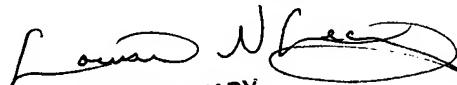
5. Claims 2-3, and 5-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

For 24 hour access to patent application information, 7 days a week, or for filing patent applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.



LOUISE N. LEARY  
PRIMARY EXAMINER

August 20, 2003